

The Peaceful Kingdom Alliance 4 Animals, Inc.

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Docket No. 00N-0989
Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Room 10-61 HFA-305
Rockville, MD 20852
fdadockets@oc.fda.gov (oc.fda.gov)

(Re: Docket No. 00N-0989)

To whom it may concern,

I am writing in support of a proposed rule that would provide public access to study design and safety information on all new or ongoing clinical trials involving either gene therapy or xenotransplantation. Both are potentially dangerous areas that the public should know about. This proposed rule only brings gene therapy and xenotransplantation in compliance with the same types of information already released to the public by other government agencies.

Because of the grave public health risks, disclosure should include additional information such as names of physicians conducting the trials and names of participating medical centers. All information should be made public except trade secrets and patient identification. The FDA must assume the sole responsibility for summarizing and distributing information submitted by the research sponsors, rather than leave it to the sponsors' discretion.

I strongly believe that because of the public health risks, legal and ethical issues, enormous cost, serious animal welfare concerns, and the failure to

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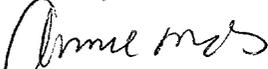
00N-0989

Please Be Kind to Animals!

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adequately assess other alternatives, all
xenotransplantation clinical trials should stop.
Moreover, the U.S. government should stop funding
xenotransplantation research.

Sincerely,


Annie Mais

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